IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
CIVIL CASE NO. 1:23-cv-00281-MR

BARBARA A. BEAVER,	)	
	)	
Plaintiff,	)	
	)	**MEMORANDUM OF**
vs.	)	**DECISION AND ORDER**
	)	
PFIZER INC.,	)	
	)	
Defendant.	)	
	)	

THIS MATTER is before this Court on Defendant's Motion to Dismiss. [Doc. 6].

I. PROCEDURAL BACKGROUND

As a preliminary matter, Barbara A. Beaver ("Plaintiff") has previously sued Pfizer Inc. ("Defendant") for negligence based on the same facts she alleges here. See Beaver v. Pfizer Inc., No. 1:22-cv-00141-MR, 2023 WL 2386776 (W.D.N.C. Mar. 6, 2023), aff'd as modified, No. 23-1297, 2023 WL 4839368, at *1 (4th Cir. July 28, 2023). This Court dismissed Plaintiff's first action with prejudice. Id. Finding no reversible error, the Fourth Circuit Court of Appeals affirmed this Court's order "as modified to reflect dismissal without prejudice," thereby allowing Plaintiff an opportunity to correct the pleading

deficiencies that resulted in the dismissal of her case. See Beaver v. Pfizer Inc., No. 23-1297, 2023 WL 4839368, at *1 (4th Cir. July 28, 2023).

On August 29, 2023, Plaintiff, appearing *pro se*, filed her second Complaint based on these facts in North Carolina state court, again alleging negligence. [Doc. 1-2]. On October 4, 2023, Defendant filed a notice of removal to federal court, alleging diversity jurisdiction pursuant to 28 U.S.C. § 1332, as Plaintiff is a citizen of North Carolina, Defendant is a corporation with citizenship in Delaware and New York, and Plaintiff alleges damages exceeding $75,000. [Doc. 1]. On October 11, 2023, Defendant filed a Motion to Dismiss for Failure to State a Claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. [Doc. 6]. On October 25, 2023, Plaintiff filed a Response in Opposition to Defendant's Motion to Dismiss. [Doc. 8]. On November 1, 2023, Defendant filed a Reply to Plaintiff's Response and on November 7, 2023, Plaintiff filed a Surreply.[1] [Docs. 9, 10]. Having now been fully briefed, this matter is ripe for disposition.

[1] Under Local Rule 7.1(e), "[s]urreplies are neither anticipated nor allowed . . . , but leave of Court may be sought to file a surreply when warranted." Plaintiff, here, failed to seek leave of Court to file her surreply. [Doc. 10]. Therefore, it is stricken. However, even if this Court were to consider Plaintiff's surreply, its conclusions would remain the same.

II. STANDARD OF REVIEW

The central issue for resolving a Rule 12(b)(6) motion is whether Plaintiff's claims state a plausible claim for relief. See Francis v. Giacomelli, 588 F.3d 186, 189 (4th Cir. 2009). In considering Defendant's motion, the allegations in the Complaint are taken as true and construed in the light most favorable to Plaintiff. Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 253 (4th Cir. 2009); Giacomelli, 588 F.3d at 190-92.

When considering a motion to dismiss, a *pro se* complaint is construed liberally, "however inartfully pleaded[.]" Booker v. S.C. Dep't of Corrs., 855 F.3d 533, 540 (4th Cir. 2017) (quoting Erickson v. Pardus, 551 U.S. 89, 94 (2007)). Although this Court accepts well-pled facts as true, it does not accept "legal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement." Consumeraffairs.com, 591 F.3d at 255; see also Giacomelli, 588 F.3d at 189. The claims need not contain "detailed factual allegations," but must contain sufficient factual allegations to suggest the required elements of a cause of action. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007); see also Consumeraffairs.com, 591 F.3d at 256. "[A] formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555. Nor will mere labels and legal conclusions suffice. Id. Rule 8 of the Federal Rules of Civil Procedure

"demands more than an unadorned, the defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

The complaint must contain "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570; see also Consumeraffairs.com, 591 F.3d at 255. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678; see also Consumeraffairs.com, 591 F.3d at 255. The mere possibility that a defendant acted unlawfully is not sufficient for a claim to survive a motion to dismiss. Consumeraffairs.com, 591 F.3d at 256; Giacomelli, 588 F.3d at 193. Ultimately, the well-pled factual allegations must move a plaintiff's claim from possible to plausible. Twombly, 550 U.S. at 570; Consumeraffairs.com, 591 F.3d at 256.

III. FACTUAL BACKGROUND

Construing the well-pled factual allegations of the Complaint as true and drawing all reasonable inferences in Plaintiff's favor, the following is a summary of the relevant facts.

Plaintiff's doctor prescribed her Celebrex, a prescription medication manufactured by Defendant, to treat her arthritis. [Doc. 1-2 at ¶ 1]. In 2020, Plaintiff was diagnosed with Stage 3 kidney disease. [Id. at ¶ 7]. Plaintiff

attributes this kidney disease to Celebrex. [Id. at ¶ 8]. She reaches this conclusion because her doctor recommended that she stop taking Celebrex due to her disease and because her kidney function gradually increased after she stopped taking the medication. [Id. at ¶¶ 6-8]. Plaintiff alleges that she has not had any other medication, health, or lifestyle changes to which the improved kidney function could be attributed. [Id. at ¶ 9]. As a result of her diminished kidney function, Plaintiff cannot take anti-inflammatories or arthritis medication and therefore experiences pain. [Id. at ¶ 10].

Plaintiff alleges that in 2005, the United States Food and Drug Administration ("FDA") "suggested" that Defendant remove Celebrex from the market due to heart and stroke complications. [Id. at ¶ 2]. Defendant did not remove Celebrex from the market, but it did add a warning label regarding potential heart and stroke complications. [Id.]. Celebrex's label does not, however, contain a warning about potential kidney damage. [Id.].

IV. DISCUSSION

As she did in her previous case, see Beaver, 2023 WL 2386776, Plaintiff alleges that if "Defendant had taken Celebrex off the market as suggested by the FDA in 2005, Plaintiff would not have been prescribed . . . Celebrex and would not have permanent kidney damage." [Doc. 1-2 at ¶ 17]. Defendant contends, as it did previously, that any state-law duty to

remove Celebrex from the market is preempted by federal law, specifically, the Food, Drug, and Cosmetic Act ("FDCA"). [See Doc. 7 at 4-7].

The Supremacy Clause of the Constitution makes evident that "state laws that conflict with federal law are 'without effect.'" Altria Grp., Inc. v. Good, 555 U.S. 70, 76 (2008) (quoting Maryland v. Louisiana, 451 U.S. 725, (1981)). A state law can be preempted via: (1) express preemption, (2) field preemption, or (3) conflict preemption. Id. at 76-77. Conflict preemption, the only type relevant here, exists where "there is an actual conflict between state and federal law," id., and the "state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" Hillsborough Cnty. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). In other words, a state law is preempted "where it is 'impossible for a private party to comply with both state and federal requirements.'" Mut. Pharm. Co., Inc. v. Bartlett, 570 U.S. 472, 480 (2013) (quoting English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990)).

In Bartlett, the Supreme Court held that a pharmaceutical company's state-law duty to strengthen a generic drug's label was preempted by the FDCA's prohibition on changes to generic drug labels because it was impossible for the company to comply with both state and federal law. Id. at

479-80. In reaching this conclusion, the Court specifically rejected the theory that conflict preemption could be avoided because the pharmaceutical company could comply with the seemingly irreconcilable state and federal laws by ceasing production of the drug altogether, stating, "[o]ur pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." Id. at 488.

Here, the Plaintiff asserts a negligence/products liability claim, which is a state law claim. However, any state-law duty Defendant may have to withdraw Celebrex from the market is preempted because the only way to comply would be to cease production of the drug altogether, the precise theory the Supreme Court rejected in Bartlett. Moreover, allowing a state-law duty to foreclose the sale of an FDA approved medication—such as Celebrex—would also frustrate the purposes of the FDA's regulatory scheme. See Gross v. Pfizer, Inc., 825 F. Supp. 2d 654, 659 (D. Md. 2011) ("The Court is aware of no state law duty that would compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce. Nor could such a state law duty exist, as it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in

interstate commerce."). For these reasons, Plaintiff's "stop-selling" theory does not state an actionable claim for negligence.

In addition to this theory, Plaintiff contends that Defendant should have never sold Celebrex and that it negligently designed the drug. [See Doc. 8 at 2-3]. However, such "should have never sold" theory is inconsistent with the supreme Court's ruling in Bartlett, where the Court stated that "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." 570 U.S. at 488. Therefore, where a pharmaceutical company cannot be made to cease acting to avoid liability, the law does not prevent it from acting at all. Moreover, allowing a state-law duty to prevent a pharmaceutical company from selling an FDA approved medication in the first instance would frustrate the purposes of the FDA's regulatory scheme, as the FDA is tasked with determining whether a drug may be sold in interstate commerce. See Gross, 825 F. Supp. 2d at 659.

Regarding Plaintiff's negligent design claim, Defendant argues that Plaintiff's Complaint is devoid of facts supporting the elements necessary to sustain" such a claim. [Doc. 7 at 8]. "Under North Carolina law, . . . a plaintiff bringing a products liability action based on negligence must prove (1) the product was defective at the time it left the control of the defendant, (2) the

defect was the result of defendant's negligence, and (3) the defect proximately caused plaintiff damage." Farrar & Farrar Farms v. Miller-St.Nazianz, Inc., 477 F. App'x 981, 984 (4th Cir. 2012) (citing Red Hill Hosiery Mill, Inc. v. MagneTek, Inc., 138 N.C. App. 70, 75, 530 S.E.2d 321, 326 (2000)). Additionally, a plaintiff must prove one of the following:

> (1) At the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.
>
> (2) At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

N.C. Gen. Stat. §§ 99B-6(a)(1)-(2).

Plaintiff's Complaint includes only conclusory allegations that Celebrex was "poorly designed" and that Defendant "negligently developed and designed the drug." [See Doc. 1-2 at ¶ 18]. However, these bare assertions and legal conclusions are not sufficient to state a claim for negligent design. See Consumeraffairs.com, 591 F.3d at 255. Rather, Plaintiff must include

sufficient factual allegations in her Complaint to suggest the required elements of a cause of action. Twombly, 550 U.S. at 555. Specifically, because she alleges negligent design, Plaintiff must make factual allegations regarding the specific ways in which the design of Celebrex is defective. See Asby v. Medtronic, Inc., No. 4:22-CV-125, 2023 WL 3551041, at *3 (E.D.N.C. May 18, 2023); Presnell v. Snap-On Securecorp., Inc., 1:20CV234, 2021 WL 1227062, at *3 (M.D.N.C. Mar. 31, 2021). Plaintiff's Complaint contains no such allegations.

Moreover, Plaintiff has not made any allegations regarding the existence of a reasonable alternative design for Celebrex, nor has she alleged that the drug is so unreasonably designed that a reasonable person would not use it, as is required to state a claim for negligent design under N.C. Gen. Stat. §§ 99B-6(a)(1)-(2). This Court is mindful of Plaintiff's *pro se* status. However, "[e]ven a pro se plaintiff . . . must allege sufficient facts 'to raise a right to relief above the speculative level' and 'state a claim to relief that is plausible on its face.'" King v. Rubenstein, 825 F.3d 206, 225 (4th Cir. 2016). Plaintiff has not done so here and as a result, her negligent design claim will be dismissed.

"[P]laintiffs do not get a dry run as a matter of right. District courts have inherent power to manage their dockets with an eye toward speedy and

efficient resolutions and part of that power is the use of with-prejudice dismissals." United States *ex rel.* Nicholson v. MedCom Carolinas, Inc., 42 F.4th 185, 196 (4th Cir. 2022) (internal citations omitted). Therefore, as this is Plaintiff's second attempt to state a claim against Defendant for negligence based on these same facts, this Court will exercise its discretion and dismiss her claims with prejudice.

O R D E R

IT IS, THEREFORE, ORDERED that Defendant's Motion to Dismiss for Failure to State a Claim [Doc. 6] is hereby **GRANTED,** and this action is **DISMISSED WITH PREJUDICE.**

IT IS FURTHER ORDERED that Plaintiff's Surreply [Doc. 10] is hereby **STRICKEN.**

IT IS SO ORDERED.

Signed: January 22, 2024

Martin Reidinger
Chief United States District Judge